TABLE OF CONTENTS

SUMMARY

This pre-announced, routine, surveillance inspection of a medical device manufacturer was conducted under Operation ID # 51414, and in accordance with Compliance Programs 7382.845B and 7881.011, Inspection of Medical Device Manufacturers. The previous inspection was conducted on 07/30-08/01/2013, and was classified NAI.

This firm manufactures radiological delivery system capital equipment medical devices. Design control activities for these devices are managed at their facility in Indianola, PA. During this inspection, management controls, corrective and preventive actions, and production and process controls were reviewed. Design controls were covered during the inspection of their Indianola facility.

Management was cooperative and made no refusals, and no FDA Form 483 was issued.

ADMINISTRATIVE DATA

Inspected firm:	Bayer Medical Care, Inc.
Location:	625 Alpha Dr Pittsburgh, PA 15238-2819
Phone:	412-767-2400
FAX:	
Mailing address:	625 Alpha Dr Pittsburgh, PA 15238-2819
Dates of inspection:	1/17/2017-1/18/2017
Days in the facility:	2

Participants: **Katelyn A Staub-Zamperini, Investigator**

At the beginning of this inspection, credentials were presented and an FDA Form 482, Notice of Inspection, was issued to Ruben (nmi) Perez, Site Manager, who identified himself as the most responsible individual at this location.

HISTORY

This firm is owned by Bayer Healthcare, and is part of the Bayer Radiology group under Bayer's Pharmaceuticals Division. This firm is registered with the FDA as Bayer Medical Care, Inc. and operates as Bayer Medrad. Firm management provided an introductory presentation on the facility overview **(Exhibit # 1)**. This firm currently maintains approximately (b) (4) employees, and produces approximately (b) (4) medical devices per year. Future FDA correspondence should be addressed to, Ruben Perez, Site Manager, and sent to:

625 Alpha Drive
Pittsburgh, PA 15238-2819

INTERSTATE (I.S.) COMMERCE

This firm utilizes the distributor, (b) (4) located in (b) (4). Products are then further distributed throughout the United States, as well as internationally.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

This firm is registered with the FDA as a medical device manufacturer and produces radiological delivery system medical devices. **Page # 7** of **Exhibit # 1** describe this firm's product lines.

Firm management stated that the Stellant CT Injector System is the highest volume product manufactured, and that the Intego PET Infusion System has been launched since the previous inspection. Firm management provided an Operation Manual for a Medrad brand Intego PET Infusion System **(Exhibit # 2)**.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Joseph Kridgen, Quality Product Steward, was present for this entire inspection. Ruben (nmi) Perez, Site Manager, was present at the start and conclusion of this inspection. Mr. Perez is the most responsible individual at this firm, and is responsible for all day-to-day operations. Mr. Perez stated that he reports to Jeff Owoc. An organizational chart is on **Page # 9** of **Exhibit # 1**.

MANUFACTURING/DESIGN OPERATIONS

During this inspection, management controls, design controls, production and process controls, and

corrective and preventive actions were reviewed. Inspectional coverage of each subsystem is as follows:

Management Controls: Monthly quality review meeting documentation, specific to this facility, was reviewed.

Production and Process Controls: Component specifications and incoming inspection activities were reviewed. An approved supplier list, as well as supplier audit documentation was reviewed. Additionally, build of materials, assembly procedures, device history records, and equipment calibration records and procedures were reviewed.

Corrective and Preventive Action: CAPA files and a "Quality Issue Assessment" was reviewed

EXHIBITS COLLECTED

1 Exhibit 1, Introductory Presentation, 10 pages
2 Exhibit 2, Operation Manual, 146 pages

ATTACHMENTS

1 FDA Form 482, Notice of Inspection, 3 pages

3/8/2017

X Katelyn A Staub-Zamperini

Katelyn A Staub-Zamperini
Investigator
Signed by: Katelyn A. Staub-zamperini -S